UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

IN RE: ORAL PHENYLEPHRINE MARKETING AND SALES PRACTICES LITIGATION	MDL NO. 1:23-MD-3089-BMC THIS DOCUMENT RELATES TO: ALL CASES

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE INITIAL STREAMLINED CONSOLIDATED NEW YORK BELLWETHER CLASS ACTION COMPLAINT

Dated: July 15, 2024

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INTRODUCTION

This case turns on a simple question: Can drug companies sell drugs they *know* do not work, while falsely advertising that they do? Under both state and federal law, the answer is "no." The burden *always* remains on a *manufacturer* to update its label to tell the truth. If the science establishes that their products do not work, they must say so.

Plaintiffs plausibly allege that Defendants violated state and federal law because they 1) knew no later than January 2016 that oral phenylephrine ("Oral PE") does not relieve sinus/nasal congestion, 2) falsely advertised and misbranded "PE Products" to consumers as doing so, and 3) conspired to defraud and mislead consumers, the public, and (for RICO purposes only, also) the FDA. Defendants seek dismissal because, they contend, their labels complied with the FDA-approved monograph (state law preemption and RICO preclusion), and because consumers did not purchase directly from them (RICO). Defendants are wrong, and they reach their conclusion only by largely—often entirely—ignoring controlling law adverse to their arguments.[1]

Defendants ignore the central premise of federal drug regulation: *manufacturers* bear responsibility for maintaining the accuracy and truthfulness of their labels at all times. *Wyeth v. Levine*, 555 U.S. 555, 570, 575 (2009). They disregard that both the Federal Food, Drug, and Cosmetic Act ("FDCA") and federal regulations governing over-the-counter ("OTC") drugs require them to make *only truthful* statements about efficacy. They ignore the Supreme Court's holding that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *Wyeth*, 555 U.S. at 575, and this Court's post-*Wyeth* recognition that "state law consumer protection statutes … continue to serve their traditional complementary role

[1] Failure to cite controlling authority is improper. NYST RPC Rule 3.3(a)(2); *Vill. of Freeport v. Barrella*, 814 F.3d 594, 609 (2d Cir. 2016). If Defendants do so for the first time on reply, Plaintiffs may request permission to file a sur-reply.

with FDCA labeling requirements," *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Pracs.* Litig., 701 F. Supp. 2d 356, 370 (E.D.N.Y. 2010). They do not acknowledge that neither the Second Circuit nor the Supreme Court has *ever* applied the indirect purchaser rule to RICO claims, and do not even cite the Supreme Court's seminal case holding that RICO standing requires only "some direct relation between the *injury* asserted and the *injurious conduct* alleged," *not* a direct relationship between the *parties*, *e.g.* a direct purchase. *Bridge v. Phoenix Bond & Indemnity. Co.*, 553 U.S. 639, 654 (2008) (cleaned up) (emphasis added). And they ignore the controlling Second Circuit preclusion case, *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d 48 (2d Cir. 2016), which rejects precisely their preclusion theory.

Plaintiffs respectfully request that the Court deny Defendants' motion.

FACTUAL BACKGROUND

Defendants' PE Products do not decongest. Compl. ¶ 3. In 1976, the FDA's Cold-Cough Panel reviewed Oral PE when it reviewed similar medications. Compl. ¶ 45. While finding the data presented on PE were "not strongly indicative of efficacy," absent safety concerns, the panel recommended approving PE as "safe and effective" at a dose of 10mg. *Id*. ¶ 46. In February 2007, the FDA Nonprescription Drug Advisory Committee ("NDAC") met to discuss evidence regarding Oral PE's efficacy. Nine of twelve panelists requested "additional clinical data … including new studies that should evaluate the decongestant effect of higher doses of Oral PE." *Id*. ¶ 60. By no later than 2016, peer-reviewed studies clearly established that Oral PE is no more effective than a placebo. *Id*. ¶ 62. Defendants knew it, *id*. ¶ 65, but did not correct their labels, and (as relevant to the RICO claim) several (individually and via an industry trade group) made false statements to regulators and the public regarding Oral PE's efficacy, *id*. ¶¶ 463-521.

On September 12, 2023, the NDAC voted 16-0 that the scientific data do not support Oral PE as an effective decongestant. *Id*. ¶ 78. Defendant Johnson & Johnson Consumer Inc. ("J&J")

quickly published a new label disclosure on its website, linking to an FDA statement regarding the NDAC's finding "that the current scientific data do not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant." *Id.* ¶ 82.

REGULATORY FRAMEWORK

The regulatory and statutory framework governing OTC drugs requires manufacturers to tell the truth about their products. The FDCA prohibits misbranding of *all* drugs, including those FDA approves. 21 U.S.C. § 352(a)(1) ("Anti-Misbranding Statute"); 21 C.F.R. § 314.170 ("All drugs"). The Anti-Misbranding statute is broad, prohibiting labels that are "false or misleading *in any particular*." 21 U.S.C. § 352(a)(1) (emphasis added). A product can be misbranded "not only" for affirmative misrepresentations "but also" implied misrepresentations and material omissions. 21 U.S.C. § 321(n). FDA regulates OTC drugs through the monograph system, codified in 21 C.F.R. Part 330, or the New Drug Application ("NDA") system, codified in 21 C.F.R. Part 314. All Defendants marketed PE Products governed by the "PE Monograph," 21 C.F.R. § 341.80, and by Part 330's general requirements for monograph drugs, 21 C.F.R. § 330.1 (the "General Regulation").[2] An OTC drug is "misbranded" under the General Regulation if it does not meet "each of the conditions contained in [Part 330] and each of the conditions contained in any applicable monograph." [3] The conditions in Part 330 include the Anti-Misbranding Statute. *See* 21 C.F.R. § 330.1(c)(1) ("[t]he product is labeled in compliance with chapter V of the [FDCA]").

The PE Monograph provides specific requirements for labeling that also require truthful statements and incorporate the Anti-Misbranding statute. It regulates four types of information on

[2] Defendant Haleon also sold one PE Product purchased by a named plaintiff, Advil Sinus Congestion & Pain, pursuant to an approved NDA. Compl. ¶ 327 (NDA No. 022565). It holds at least one other PE NDA. (NDA No. 022113).

[3] Defendants use an ellipsis to omit the crucial requirement that labeling must comply with "each condition contained" in Part 330, Br. at 16, deflecting from their noncompliance with 21 CFR Part 330.

the label: the "[s]tatement of identity," "[i]ndications," "[w]arnings," and "[d]irections." 21 C.F.R. § 341.80. A *statement of identity* describes the category of drug at issue, such as "antacid," "analgesic," and "antihistaminic." 21 C.F.R. § 201.61(b); *see* 21 C.F.R. § 330.5 (listing "drug categories" for OTC drugs subject to monograph system). It reflects the FDA's attempt to group OTC drugs by "the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug" sold under the monograph system. 21 C.F.R. § 201.61(b). A drug's *indication* explains its effects, *i.e.*, how it works. Plaintiffs challenge only the *indications* section of the Defendants' PE Products, *not* the *statements of identity*, *warnings*, or *directions*.

For the *statement of identity*, *warnings*, and *directions*, the General Regulation requires manufacturers to include verbatim the "exact language" in the monograph. 21 C.F.R. § 330.1(c)(2). For the *indications*—the requirement Plaintiffs rely on—the manufacturer must include *either* the language in the monograph "*or alternative truthful and nonmisleading statements* describing only those indications for use … established in an applicable monograph, *subject to the provisions of section 502 of the act relating to misbranding ….*"[4] *Id.* (emphasis added). The PE Monograph identifies two *indications*—"[f]or the temporary relief of nasal congestion" or "[t]emporarily relieves nasal congestion"—that a manufacturer may use "as appropriate." 21 C.F.R. § 341.80(b). But manufacturers may also use "[o]ther truthful and nonmisleading statements, describing only the indications for use that have been established and listed in" the PE Monograph. This flexibility is provided by the General Regulation provision permitting "alternative truthful and nonmisleading statements," subject to the Anti-Misbranding statute. 21 C.F.R. § 341.80(b). The FDA's 1986 final rule adopted this "flexibility" policy for describing "indications for use" to "allow manufacturers" to "develop[] their own wording," a

[4] Section 502 of the FDCA has been codified as 21 U.S.C. § 352—the Anti-Misbranding Statute.

departure from a prior rule requiring use of the *exact* language from a monograph for *indications*. 51 Fed. Reg. 16258-01, 16262. This change was essential to "meet consumers' needs for accurate labeling information," to "improve patients' understanding of OTC drug products," and to "assist manufacturers in writing clear communications to consumers." 51 Fed. Reg. at 16258. It also "allow[s]" manufacturers "to change label information" on their own, "without complying with unnecessary FDA procedures." *Id.*

As they must, the FDA's final rule and regulations thus implemented Congress's mandate in the Anti-Misbranding Statute: "*Regardless* of which alternative manufacturers choose"—indications listed in the monograph or "alternative" language a manufacturer develops—"FDA regulations require that the labeling of OTC drug products be *clear and truthful in all respects, not false or misleading in any particular*." 51 Fed. Reg. 16259 (emphasis added). Reflecting this regulatory scheme, the FDA explained in an amicus brief that a drug with FDA-approved labeling may become "misbranded" based on new and scientifically significant information not before the FDA at time of its approval. *Mut. Pharm. Co., Inc. v. Bartlett*, 2013 WL 314460, at *12 (U.S. Jan. 22, 2013). The Supreme Court agreed. *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 487 n.4 (2013).

ARGUMENT

I. Plaintiffs' State-Law Claims Are Not Preempted

"Congress does not cavalierly pre-empt state-law causes of action." *Wyeth*, 555 U.S. at 565 n.3 (citation omitted). With respect to state-law consumer protection claims like these, "the historic police powers of the States" are not preempted "unless that was the clear and manifest purpose of Congress." *Altria Grp., Inc. v. Good*, 555 U.S. 70, 77 (2008). The preemption analysis is guided by the principle that "the manufacturer bears responsibility for the content of its label at all times," and the manufacturer *must* update its label to reflect new scientific information so it "remain[s] adequate as long as the drug is on the market." *Wyeth*, 555 U.S. at 570-71 (cleaned up); *see Merck*

Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 304 (2019)(recognizing that information changes and "new information may require changes to the drug label"). That principle applies to manufacturers of OTC drugs, who must revise their labeling as soon as there is new evidence. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 42 (2011).

Under both federal and state law, Defendants must tell the truth about their drugs, including on their labels. This common-sense result is required by the General Regulation and the PE Monograph. FDA regulations require *all* OTC efficacy statements to be truthful and subject to the Anti-Misbranding statute, "regardless" of the language the manufacturer employs. 51 Fed. Reg. 16259. Indeed, manufacturers of OTC drugs subject to a monograph may even bypass individualized FDA review and change their labels unilaterally to include "truthful and nonmisleading" statements, including specifically an update warranted by new scientific information. *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75 (2d Cir. 2013); 21 C.F.R. §§ 330.1(c)(2), 341.80(b). Holders of an approved NDA for an OTC drug can also change their labels based on "newly acquired information," without prior FDA approval, through the Changes Being Effected ("CBE") regulation. *See* 21 C.F.R. § 314.70(c)(6)(iii); *Wyeth*, 555 U.S. at 568. Preemption principles regarding "tightly regulated prescription drugs" are "undoubtedly relevant" to less-regulated OTC monographed drugs. *In re Acetaminophen ASD-ADHD Prods. Liab. Litig.*, 2023 WL 4976589, at *3 (S.D.N.Y. Aug. 3, 2023). As with prescription drugs, FDA approval of a monograph "does not represent a finding that [PE Products], as labeled, can never" be challenged by "application of state law." *Wyeth*, 555 at 592 (Thomas, J., concurring).

A. Plaintiffs' State Law Claims Are Not Expressly Preempted.

In passing Section 379r, Congress narrowly preempted only state-law "requirements" that 1) are "different from or in addition to, or … otherwise not identical with," the FDCA, and 2) "that

relate[] to the regulation of a drug." Neither condition is met here.[5]

1. New York imposes requirements "identical with" federal requirements.

Nothing prohibits state law from imposing "a requirement that is identical to" requirements under federal law. 21 U.S.C. § 379r(f); *see Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996)(no preemption where state law "parallel[s] federal requirements"). In OTC drug cases, courts routinely hold that Section 379r does not preempt claims alleging state law violations that parallel federal misbranding law.[6] That makes sense: "Plaintiffs' grievances—[about a product's efficacy], despite the claims on their labels—fall squarely within the realm of conduct that would violate the FDCA." *Booker*, 2021 WL 4340489, at *7. Both federal law (*e.g.*, 21 U.S.C. § 352(a)(1)) and New York law (*e.g.*, N.Y. Educ. Law § 6815(2)(a), N.Y. Gen. Bus. Law § 349, *et seq*.) prohibit the sale of misbranded drugs. *See Reid v. GMC Skin Care USA Inc.*, 2016 WL 403497, at *10 (N.D.N.Y. Jan. 15, 2016) (state law "require[s] Defendant to truthfully state … efficacy … or not sell its products," consistent with federal law). Plaintiffs' state law claims *all* focus on Defendants' false advertising of, and misrepresentations and omissions about, PE Products' efficacy to consumers. Compl. ¶¶ 9, 11, 375-378, & Counts 1-6.

Defendants' attempt to create a conflict between state law and the PE Monograph fails. Defendants make *no* argument regarding preemption of OTC drugs approved under an NDA, like Haleon's Advil Sinus Congestion & Pain, Compl. ¶ 327. As for PE Products marketed under the Monograph, Defendants argue 1) their labeling of PE Products complied with the Monograph, and

[5] Defendants cite *Sapienza v. Albertson's Cos., Inc.*, 2022 WL 17404919 (D. Mass. Dec. 2, 2022) for "a broad reading of Section 379r," Br. at 12, but that is contrary to *Wyeth* and belied by the legislative history itself: "it [was] not the intent … to affect State laws that prohibit false and misleading advertising or to prohibit unsubstantiated claims for nonprescription drugs." 105 Cong. Rec. S9844 (daily ed. Sept. 24, 1997)

[6] *See Prescott v. Ricola USA, Inc.*, 2024 WL 1892290, at *2-3 (N.D. Cal. Apr. 30, 2024); *Booker v. E.T. Browne Drug Co., Inc.*, 2021 WL 4340489, at *7 (S.D.N.Y. Sept. 23, 2021); *Dayan v. Swiss-Am. Prod., Inc.*, 2017 WL 9485702, at *4 (E.D.N.Y. Jan. 3, 2017); *Souter v. Edgewell Pers. Care Co.*, 542 F. Supp. 3d 1083, 1098 (S.D. Cal. 2021).

2) because such compliance forbids their PE Products from being misbranded regardless of new scientific information, Plaintiffs' claims are preempted. Neither argument is persuasive.

a. Defendants' labeling does not conform to the Monograph.

Defendants' statement that "no Plaintiff disputes that the medicines comply with the monograph," Br. at 7, is false. Plaintiffs allege Defendants "violated … the FDCA and the FDA's implementing rules and regulations," Compl. ¶ 372, and Defendants agree a "monograph is a 'detailed regulation' … for each class of OTC drug." Br. at 3. Simply put: Defendants' labels do not comply with the monograph, which requires them to tell the truth, and they made false claims and material omissions about PE Products' *indications*. Under the General Regulation, Defendants "shall" use the indication language in the monograph *or* "alternative truthful and nonmisleading statements." 21 C.F.R. § 330.1(c)(2); *see* 21 C.F.R. § 341.80(b). The PE Monograph allows Defendants to label PE Products' *indications* with "the phrase listed in" the PE Monograph only "as appropriate." 21 C.F.R. § 341.80(b). Once new science proved PE Products do not decongest, it was not "appropriate," "truthful," or "nonmisleading" to say the opposite. Defendants violated the Anti-Misbranding Statute's command not to misbrand labeling as to "any particular," 21 U.S.C. § 352(a)(1), as well as FDA's regulations, 21 C.F.R. § 330.1(c)(1)-(2); 21 C.F.R. § 341.80(b); 51 Fed. Reg. 16259 ("[R]egulations *require* that the labeling of [PE] products be clear and truthful *in all respects*, not false or misleading in any particular.") (emphasis added).

Defendants contend "the FDA requires products with phenylephrine … to state that they are indicated '[f]or the temporary relief of nasal congestion' or 'temporarily relieves nasal congestion.'" Br. at 14. Yet Defendants had flexibility *not* to use that "required" language, and they admit to making other claims "relating to phenylephrine's efficacy" not "required" by the PE

Monograph,[7] claiming "the FDA does not prohibit [them] from making these statements." *Id.* But the PE Monograph requires labels to contain only "truthful and nonmisleading statements." 21 C.F.R. § 341.80(b). Defendants knew Oral PE does not work and chose to lie.

To be sure, *truthful* labeling must describe only the indication identified in the Monograph.[8] Nothing, however, permits "truthful" statements in an indication to be something the manufacturer knows to be false. The FDA does not—and cannot—compel Defendants to lie. *See* 21 U.S.C. § 352(a)(1); 21 C.F.R. § 314.170. To conclude otherwise would vitiate the reasons the FDA enacted its flexibility policy: to "meet consumers' needs for accurate labeling information" and "improve patients' understanding of OTC drug products," by having manufacturers "change label information" without jumping through regulatory hoops. *See* 51 Fed. Reg. 16258.

Defendants' argument that truthfully describing PE Products' efficacy would somehow render them "misbranded," contravenes the FDA's final rule, which provides that OTC drugs are misbranded only when they *exceed* approved *indications*, not when they are updated to correct ones no longer supported by science. 51 Fed. Reg. 16258-01 at 16260 ("FDA intends … to ensure that any alternative language that manufacturers use does not go *beyond* the approved indications for use, thereby causing the drug to become a 'new drug' or 'misbranded.'") (emphasis added).[9]

Defendants argue that the PE Monograph's *statement of identity* as a "nasal decongestant," 21 C.F.R. § 341.80(a), requires them to describe falsely their PE Products' *indications*. Br. at 13-

[7] *E.g.*, Compl. ¶ 68 (depicting a product label that purports to "temporarily relieve[] sinus congestion").

[8] For example, labeling for PE could not describe indications for use covered by, *e.g.*, OTC Monograph M013 at § M013.50(b)(1) ("For the temporary relief of minor aches and pains").

[9] The final rule addressed concerns that the flexibility policy would "benefit unscrupulous manufacturers," allowing them to make "bolder claims." 51 Fed. Reg. 16258-01 at 16259. The FDA explained that "there can be various ways of accurately stating the same thing" and "the agency will use the monograph language as its standard in determining whether alternative statements are accurate" to ensure manufacturers do not go "beyond" the approved indications. *Id.* at 16259-60. These comments were intended to combat *broader* rather than *narrower* efficacy claims, and do not forbid manufacturers from truthfully disclosing their drug is *less* effective than the FDA was led to believe.

14. But Plaintiffs do *not* challenge the *statement of identity* on Defendants' labels. The regulations governing the *statement of identity* merely require manufacturers to identify the "general pharmacological category[]" of an OTC drug. 21 C.F.R. § 201.61. The *indications* section is where "uses" are described, 21 C.F.R. § 330.1(c)(2), and where *efficacy* claims are made. Nothing in the *statement of identity* relieves Defendants of their obligation to make "truthful and nonmisleading" statements about *indications*. *Id.* If their drugs do not work, they must say so.

b. The Monograph does not preempt parallel misbranding claims supported by new scientific information.

Even assuming Defendants' labeling satisfies the PE Monograph's requirements—it does not—Plaintiffs' claims survive: Defendants had an independent obligation to update their labels to reflect new scientific information, an obligation that persists "at all times." *Wyeth*, 555 U.S at 570-71. Plaintiffs' claims are not preempted unless Defendants show they "fully informed the FDA" of the need for a label change and "the FDA, in turn, informed [them] that the FDA would not approve changing [their PE] drug's label…." *Albrecht*, 587 U.S. at 303. That admonition, combined with the Supreme Court's recognition that drugs with FDA-approved labels can become misbranded "based on new and scientifically significant information that was not before the FDA," *Bartlett*, 570 U.S. at 487 n.4., reflects a common-sense principle: PE Products *became misbranded* when new scientific information revealed their labels to be inaccurate and misleading. As Justice Alito explained, "[t]he misbranding statute requires a manufacturer to pull even an FDA-approved drug from the market when it" fails to comply with the Anti-Misbranding Statute. *Id.*

This is not some radical result, but merely a recognition that science develops and "new information may require changes to the drug label." *Albrecht*, 587 U.S. at 304; *Wyeth*, 555 U.S. at 570-71; *In re Acetaminophen*, 2023 WL 4976589, at *3 (rule is "undoubtedly relevant" to less-regulated OTC monographed drugs). Congress and the FDA neither intended nor mandated that

drug labels be frozen in time in the face of contrary science. They require the opposite. To say that a manufacturer may "not market a drug without federal approval (*i.e.*, without an FDA-approved label) is not to say that federal approval gives [manufacturers] the unfettered right, for all time, to market [their drugs] with the specific label that was federally approved." *Wyeth*, 555 U.S. at 592 (Thomas, J., concurring). FDA approval of the PE Monograph "does not represent a finding that the drug, as labeled, can never" be challenged by "application of state law." *Id.* Once scientific consensus on Oral PE's efficacy emerged, Defendants were obliged to update their labels.[10] They did not.

Defendants' argument that their hands were somehow tied and they "cannot independently alter disclosures," Br. at 18, n.4, is also flatly contradicted by *their own conduct*. Following the NDAC's meeting, J&J unilaterally changed its Sudafed website to cross-reference the NDAC's finding that "scientific data do not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant." Compl. ¶ 82.[11] *Nothing* prohibited J&J—or any other Defendant—from making more fulsome disclosures when scientific consensus emerged by 2016 that PE Products do not decongest. Their *failure* to do so violated federal and state requirements. *See* 21 U.S.C. § 321(n); Compl. ¶ 387, Count 6.

Recognizing as much, the court in *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 546 F. Supp. 3d 1284, 1305 (S.D. Fla. 2021), refused to find similar misbranding claims preempted. The OTC drug manufacturers argued there, as here, that "when the FDA approves a drug for OTC status, the drug is not misbranded … because, inter alia, the label is not false or misleading." *Id.* at 1306

[10] An FDA staffer's stray remark that PE Products are still "considered generally recognized as safe and effective," Br. at 14, is not "agency action carrying the force of law" and cannot preempt, *see Albrecht*, 587 U.S. at 316; *see also id.* at 322 (Thomas, J., concurring) (such comments do not reflect "a final agency action with the force of law ….").

[11] Such statements are "part of the product's labeling." *United States v. Innovative Biodefense, Inc.*, 2019 WL 2428670, at *4 (C.D. Cal. Feb. 22, 2019) (collecting cases).

(citing 21 C.F.R. § 331.10(a)(4)(v)). Crediting plaintiffs' allegations that new scientific information rendered a label inaccurate, the court noted that in *Bartlett*, "the FDA took the position that if a drug were alleged to be misbranded due to new, scientifically significant information that the FDA did not previously possess, the claim would not be pre-empted." *Id.* And, relying on *Wyeth*, the court rejected the argument that "it is impossible to allege an OTC drug is misbranded (when it conforms to its approved label) [.]" *Id.* at 1307. This Court should conclude the same.

c. Defendants' cited authority does not support preemption.

Defendants largely pin their preemption defense on *Critcher* v. *L'Oreal USA, Inc.*, 959 F.3d 31 (2nd Cir. 2020), a cosmetics labeling case about dispensable quantity, not a drug regulation or monograph, where plaintiff "admit[ted]" the packaging "compl[ied] with federal labeling requirements." *Id* at 36. Here, Plaintiffs allege Defendants' labels and other statements *violate* federal (and state) requirements. Nor did *Critcher* involve new scientific information. Plaintiff claimed information FDA *did not* mandate *should* have been disclosed (dispensable quantity), rather than the information FDA *did* require (net quantity). *Id.* at 36-38.[12] Plaintiff alleged no *lies*.

The district court cases Defendants cite are inapposite for at least two reasons. First, the challenged conduct there admittedly *complied* with relevant FDA regulations. *Carter v. Novartis Consumer Health, Inc.*, 582 F. Supp. 2d 1271, 1282 (C.D. Cal. 2008) ("Plaintiffs do not allege that Defendants fail to comply with FDA regulations … so none of their claims are parallel enforcement claims."); *Goldstein v. Walmart, Inc.*, 637 F. Supp. 3d 95, 103 (S.D.N.Y. 2022) (similar); *Lester v. CVS Pharmacy, Inc.*, 2024 WL 1312935, at *5-6 (S.D.N.Y. Mar. 27, 2024); *Seale v. GSK Consumer Health, Inc.*, 2024 WL 1040854, at *6 (C.D. Cal. Feb. 27, 2024) (no dispute label conformed to monograph). Second, they did not involve new scientific information

[12] *Cf. O'Connor v. Henkel Corp.*, 2015 WL 5922183, at *11-12 (E.D.N.Y. Sept. 22, 2015) (similar claims preempted).

about indications. In *Lester*, for example, plaintiff cited no new evidence disproving efficacy. *See also Bowling v. Johnson & Johnson*, 65 F. Supp. 3d 371 (S.D.N.Y. 2014) (no new science); *Singo v. Ricola USA, Inc.*, 2024 WL 196709 (S.D.N.Y. Jan. 18, 2024) (same); *Colella v. Atkins Nutritionals. Inc.*, 348 F. Supp. 3d 120 (E.D.N.Y. 2018) (same).

The pre-*Wyeth* cases Defendants cite all (improperly) placed the burden of updating labels on the FDA, not manufacturers. *See Mills v. Warner-Lambert*, 581 F. Supp. 2d 772, 782, 786 (E.D. Tex. 2008) (FDA could withdraw approval of a drug based on new evidence); *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006) (the FDA could "amend the regulations and requirements it imposed" in the face of "later-acquired knowledge.") But per *Wyeth*, the *manufacturer*, not the FDA, must update the label when new science so requires.[13]

d. Plaintiffs' express warranty claims are saved from preemption

Plaintiffs' express warranty claims are not preempted under the product liability law savings clause of 21 U.S.C. § 379r(e). Under New York law, "a plaintiff can assert claims for injury due to an allegedly defective product under theories of negligence, strict products liability, and breach of express or implied warranty." *Delgado v. Universal Beauty Prod., Inc.*, 2024 WL 1298509, at *1 (2d Cir. Mar. 27, 2024) (citing *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 106 (1983)). While the breach of warranty claim exists under the rubric of New York product liability law, the Court should "construe and apply this separate remedy in a manner that remains consistent with its current roots in contract law." *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 259 (1995); *see also Fanok v. Carver Boat Corp., LLC*, 576 F. Supp. 2d 404, 411 (E.D.N.Y. 2008) ("[W]hen tort theories are brought together with contract or warranty theories, the theories often

[13] Defendants argue it is irrelevant whether the FDA approved specific label language, Br. at 15. That misconstrues Plaintiffs' claim: they allege new scientific evidence required Defendants to *update* their labels with *truthful* language.

remain distinct, and different analyses and consequences can flow from them.").[14]

2. State-law claims unrelated to the Monograph are unaffected by Section 379r.

Even under Defendants' expansionist (and faulty) preemption argument, not *all* of Plaintiffs' state-law claims would be preempted. As Defendants acknowledge, claims "outside the scope of the relevant federal requirements" are not preempted. Br. at 11; *LeBoeuf v. Edgewell Pers. Care Co.*, 2023 WL 5432265, at *9-10 (N.D.N.Y. Aug. 23, 2023). Plaintiffs allege such claims.

Defendants' preemption defense targets only labeling requirements relating to the PE Monograph, *see* Br. at 14, but many of Plaintiffs' claims bear no connection to those federal "requirements." Defendants made strength and effectiveness representations about PE Products, including ones purchased by all but one Plaintiff—*e.g.* "maximum strength" and/or suitability for "severe" symptoms—that fall entirely outside the PE Monograph's purview. Compl. ¶¶ 19-26; Dkt. 200-1 (listing products). The PE Monograph does not discuss individualized or comparative "strength" of Oral PE, nor that Oral PE is effective for "severe" congestion. Defendants do not and cannot claim such representations are governed by the PE Monograph. Likewise, some of Plaintiffs' claims do not relate to labeling and packaging or to the PE Monograph at all, but rather representations Defendants made in stores, on their websites, in radio, television, or other online advertisements. Compl. ¶¶ 145, 168, 451. Defendants' attempt to lump all claims together is improper and disregards the limitations of Section 379r's preemptive scope.

B. Plaintiffs' State-Law Claims Are Not Impliedly Preempted.

1. It is not impossible to comply with identical state and federal laws.

"Impossibility pre-emption is a demanding defense." *Wyeth*, 555 U.S. at 573. Defendants must show it is truly "impossible for [them] to comply with both federal and state requirements."

[14] Unlike *Goldstein*, 637 F.Supp.3d at 113 n.7, here only New York consumers bring these claims.

Id. at 571. The "possibility of impossibility [is] not enough." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 n.8 (2011) (cleaned up). Both New York and federal law require "[m]anufacturers of [OTC] drugs" to "revise their labeling" to be truthful and nonmisleading when faced with new evidence, *Siracusano*, 563 U.S. at 42. Thus, it is not "impossible" to follow both. NDA holders like Haleon can update their labels based on "newly acquired information" through the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii), and because "the CBE regulation permits changes… a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both," *Albrecht*, 587 U.S. at 315.[15] Manufacturers of monograph OTC drugs have even more leeway. The regulations even allow manufacturers to include "alternative truthful and nonmisleading statements" "subject to the provisions of section 502 of the act relating to misbranding." 21 C.F.R. §§ 330.1(c)(2), 341.80(b). Tellingly, Defendants relegate *Wyeth* and its progeny to a footnote, proclaiming that drug manufacturers cannot unilaterally change their labels. Br. at 18. Defendants cite no applicable authority and fail to distinguish statutory law and caselaw establishing otherwise. *PLIVA* does not support their position, as it involved *generic* drug manufacturers that, unlike OTC drugmakers, were prohibited from unilaterally changing their labels. *See PLIVA*, 564 U.S. at 614.

Judge Cote recently rejected this same argument, asking "could the manufacturer have unilaterally changed the label … without violating [the OTC drug monograph and other] … applicable regulations?" *In re Acetaminophen ASD-ADHD Prods. Liab. Litig.*, 2022 WL 17348351, at *7 (S.D.N.Y. Nov. 14, 2022). There, as here, "[t]he answer is yes." *Id.* Because the monograph and regulations "do not alter [the] responsibility" of a manufacturer over its label, and

[15] Citing nothing, Defendants argue that CBE applies to "prescription drugs but not over-the-counter drugs." Br. at 18 n.4. But the CBE regulation's plain terms apply to "the holder of an approved NDA." 21 C.F.R. § 314.70(a), (c)(6).

monograph drugs "do not need FDA approval of their labels …," "[a] manufacturer of an OTC drug sold under the monograph system is permitted to change its label so long as it meets the requirements of its monograph and other applicable OTC drug regulations." *Id.* at *7, *10; *see In re Tylenol*, 144 F. Supp. 3d 699, 730 (E.D. Pa. 2015).

Citing *Bartlett*, Defendants argue they cannot "stop selling" PE Products. Br. at 19. Nonsense. *Bartlett* recognized a manufacturer's duty "to pull even an FDA-approved drug from the market" when it is misbranded, *i.e.* a federal requirement to stop selling. 570 U.S. at 487 n.4. The discussion in *Bartlett* Defendants invoke involved conflicting state and federal law, and a *generic* drug manufacturer unable to change its label under federal law. *Id* at 488. "Stop selling" is a well-recognized remedy for state-law claims that parallel federal requirements. *See Langan v. Johnson & Johnson Consumer Cos., Inc.*, 95 F. Supp. 3d 284, 291 (D. Conn. 2015); *Jovel v. Boiron Inc.*, 2013 WL 12164622, at *11 (C.D. Cal. Aug. 16, 2013); *Souter*, 542 F. Supp. 3d at 1098. The cases Defendants cite involved failure-to-warn claims where the benefits of the drug are weighed against risks. *See, e.g.*, *Bartlett*, 570 U.S. at 484 ("Given the impossibility of redesigning sulindac, the only way for Mutual to ameliorate the drug's risk-utility profile—and thus to escape liability—was to strengthen the presence and efficacy of sulindac's warning.") (cleaned up). Here, no such weighing is required: Oral PE has no more utility than a placebo. *See, e.g.* Compl. ¶ 62.

2. Plaintiffs' claims do not pose an obstacle to Congress's purpose.

Finally, Defendants argue Plaintiffs' claims are impliedly preempted because they present an obstacle to Congress's objective of establishing a uniform federal regulatory regime for OTC medication. Br. at 19-21. Defendants obfuscate Congress's "purposes and objectives." Congress enacted the FDCA because of "increasing[] concern[] about unsafe drugs and fraudulent marketing." *Wyeth*, 555 U.S. at 566. Both the statutory and regulatory frameworks make clear that Congress intended to strike a careful balance between a uniform federal regulatory system for drug

labeling and traditional state regulation. *Cf. Bates v. Dow Agroscis. LLC*, 544 U.S. 431, 451 (2005) ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of" federal statutes). Had Congress wanted to preempt *all* state regulation of OTC drugs, it could have explicitly forbidden parallel enforcement. *Id.* at 448-49. It did not. *See Bayer*, 701 F. Supp. 2d at 370 (Congress "preserved the right of individuals to bring common law suits" regarding "effectiveness.").

Defendants' "concern" about "50 states" adopting "50 different approaches," Br. at 20, is easily debunked. Plaintiffs' claims mirror the FDA's (and the FDCA's) mandatory, uniform approach: manufacturers must truthfully and accurately describe their products' indications. Defendants argue that being accountable to a jury for false statements would somehow upset the FDCA's scheme. Br. at 20. The Supreme Court rejected this reasoning: "lay juries are in no sense anathema to [the FDCA's] scheme: In criminal prosecutions for "violation of [FDCA] provisions, *see* [21 U.S.C. § 333], juries necessarily pass on allegations of misbranding." *Bates*, 544 U.S. at 448. The regulatory scheme contemplates that *manufacturers* bear responsibility for the truthfulness of their labels for as long as the drugs are on the market because they, not the FDA, are most able to keep abreast of new science regarding their drugs.

II. Plaintiffs Plead A Viable RICO Claim.

Defendants contend that Plaintiffs' RICO claim fails because it is 1) barred by the indirect purchaser rule and 2) precluded by the FDCA. Both arguments are atextual and contrary to controlling Supreme Court and Second Circuit caselaw Defendants do not bother to cite.

A. The Indirect Purchaser Rule Does Not Apply To RICO Claims.

Neither the Supreme Court nor the Second Circuit has ever applied the bright-line antitrust indirect purchaser rule from *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) to civil RICO claims, or otherwise limited the right to sue under RICO to only those in *privity* with defendants. To the

contrary, the Supreme Court held in *Bridge* that RICO standing requires "some direct relation between the *injury* asserted and the *injurious conduct* alleged," *not* a direct relationship or direct purchase. 553 U.S. at 654 (cleaned up) (emphasis added) (quoting *Holmes v. Sec. Inv. Prot. Corp.*, 503 U.S. 258, 268 (1992)).[16] The "term 'direct' should merely be understood as a reference to the proximate-cause enquiry," nothing more. *Holmes*, 503 U.S. at 274 n.20. The Second Circuit consistently affords RICO standing to those directly *injured* by the misconduct, rather than just direct *purchasers*. *See Empire Merchs., LLC v. Reliable Churchill LLLP*, 902 F.3d 132, 142 (2d Cir. 2018) (standing test is whether conduct "directly caused [plaintiff's] injury").[17]

For good reason. There is *no* textual support in RICO for an indirect purchaser rule. The statute expressly allows "[a]ny person injured in his business or property by reason of" racketeering activities to file suit, 18 U.S.C. § 1964(c), and "[t]here is no room in the statutory language for an additional… requirement." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 495 (1985).[18] "RICO is read broadly" so as "to effectuate its remedial purposes," which "are nowhere more evident than in the provision of a private action for those injured by racketeering activity," and "private litigants [can] use RICO" as a "tool for everyday fraud cases." *Id.* at 498-99.

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[16] *See also Hemi Grp., LLC v. City of N.Y., N.Y.*, 559 U.S. 1, 10 (2010) (standing for "direct victim[s] of th[e] conduct"); *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451, 458 (2006) (same).

[17] *See also* e.g. *Alix v. McKinsey & Co.*, 23 F.4th 196, 203 (2d Cir. 2022); *Cruz v. FXDirectDealer, LLC*, 720 F.3d 115, 120 (2d Cir. 2013); *Motorola Credit Corp. v. Uzan*, 322 F.3d 130, 135 (2d Cir. 2003); *Baisch v. Gallina*, 346 F.3d 366, 372 (2d Cir. 2003); *Hecht v. Com. Clearing House, Inc.*, 897 F.2d 21, 23 (2d Cir. 1990); *Sperber v. Boesky*, 849 F.2d 60, 64 (2d Cir. 1988).

[18] The Supreme Court has repeatedly *rejected* attempts to impose extra-statutory requirements. *See Bridge*, 553 U.S. at 654 (rejecting proposed "implicit" requirement of reliance); *Boyle v. United States*, 556 U.S. 938, 945, 948 (2009) (rejecting attempt to impose limitation on enterprise to certain "structural attributes"); *Sedima*, 473 U.S. at 479 (rejecting requirement of a "racketeering injury"); *H.J. Inc. v. Nw. Bell Tel. Co.*, 492 U.S. 229, 245, 248 (1989) (rejecting "a narrowing construction of the Act's expansive terms" limited "to combat organized crime"); *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 257 (1994) (rejecting limitation to "economic motive"); *Cedric Kushner Prom., Ltd. v. King*, 533 U.S. 158, 163 (2001) (rejecting limitation against single-employee enterprise).

Defendants' only basis for importing this antitrust rule into RICO is that Congress modeled § 1964(c) on the civil provision of the federal antitrust laws. But Congress intended to avoid imposing "inappropriate and unnecessary obstacles in the way" of private RICO litigants. *Sedima*, at 497-98 (cleaned up). This is why *Sedima* refused to require a "racketeering injury" counterpart to "antitrust injury." *Id.* at 495. In reversing dismissal of a RICO claim, the Second Circuit followed the Supreme Court's directive "not to import into RICO barriers to standing that are 'appropriate in a purely antitrust context' and not adapted to the purposes of RICO." *Horn v. Med. Marijuana, Inc.*, 80 F. 4th 130, 135 (2d Cir. 2023) (quoting *Sedima*), *cert. granted* 144 S.Ct. 1454. Grafting antitrust limitations onto RICO standing would also usurp the Second Circuit's proximate cause standard. As *Horn* explained: "by enacting a proximate-cause limitation on RICO standing, Congress made a judgment concerning the permissible degree of attenuation between a predicate act and a redressable RICO injury." 80 F.4th at 138.

Nor do the policy rationales for applying the indirect purchaser rule in antitrust apply (or make sense) in RICO. The indirect purchaser rule limits antitrust standing to direct purchasers for three policy reasons: "(1) facilitating more effective enforcement of antitrust laws; (2) avoiding complicated damages calculations; and (3) eliminating duplicative damages against antitrust defendants." *Apple Inc. v. Pepper*, 587 U.S. 273, 280, 285 (2019). In the antitrust context, the direct purchaser is always harmed by the anticompetitive conduct and well-situated to sue for all the direct damages caused. By contrast here—and in RICO claims more generally—the injured party need not be (and rarely is) in direct privity with the defendants, yet suffers *all* of the damages. It is thus logical that the proximate cause analysis for RICO standing focuses on *directly injured*

victims, while the antitrust laws focus on *direct purchasers*.[19]

If RICO required privity, legions of cases in which courts upheld RICO claims against standing challenges would be wrongly decided, starting with *Bridge*. There, the Supreme Court held that neither privity nor first-party reliance is required to establish a RICO fraud claim. *Bridge*, 553 U.S. at 649; *see also*, *Alix*, 23 F.4th at 206 (reversing dismissal of RICO claim and concluding competitor not in privity had standing). Plaintiffs in *Bridge* and *Alix* bought nothing from—indeed had no dealings (direct or indirect) with—defendants in those cases.

Plaintiffs' injuries here are far less attenuated than the plaintiffs in *Bridge* or *Alix*, and they readily satisfy the Second Circuit's proximate cause test. Unlike the indirect purchasers in antitrust cases, Plaintiffs are the direct, intended, and *only* parties injured by Defendants' fraudulent scheme. Intermediaries—wholesalers and retailers—only *benefitted* from the increased consumer demand resulting from Defendants' deception. Compl. ¶ 521. Accordingly, they likely lack Article III standing, likely cannot establish proximate cause, and have no incentive to sue Defendants.[20] Here, as in *Bridge*, "there are no independent factors that account for [Plaintiffs'] injury, there is no risk of duplicative recoveries by plaintiffs removed at different levels of injury from the violation, and no more immediate victim is better situated to sue." 553 U.S. at 658.

Defendants do not cite *Bridge*, *Sedima*, *Horn*, or *Alix*. Instead, they mischaracterize *Sperber v. Boesky*, 849 F.2d 60 (2d Cir. 1988), and cite a few pre-*Bridge* Circuit cases involving purely derivative injuries, along with a few unpersuasive out-of-circuit district court cases.

[19] *See In re Neurontin Marketing and Sales Practices Litigation*, 712 F.3d 21, 34-36 (1st Cir. 2013) (explaining *Bridge* and *Holmes* and the difference between the RICO and antitrust policies and tests).

[20] *See Schwab v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 992, 1053 (E.D.N.Y. 2006), *rev'd on other grounds*, *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008) (rejecting application of *Illinois Brick* to bar RICO claim by remote purchasers of product).

Isolating a single clause in *Sperber*, Defendants cobble together a statement found nowhere in it, contending that the court "observ[ed] that indirect consumer purchasers 'probably cannot recover under RICO, just as they cannot recover under the anti-trust laws.'" Br. at 22. But the Second Circuit did not hold that "the indirect purchaser rule applies to civil RICO claims," or even use the phrase "indirect purchasers" as Defendants imply. Instead, it affirmed the dismissal of the RICO claim there based on the lack of *proximate cause*. 849 F.2d at 65. The court referenced *Illinois Brick* only to state that a consumer with indirect injuries "cannot recover under the antitrust laws;" it said *nothing* about a RICO claim where, as here, plaintiffs are the injured party and direct target of the fraud. *Id.* at 64. And the court acknowledged *Sedima*'s holding that Congress did *not* intend to import antitrust standing into RICO. *Id.*[21] *Sperber* thus confirms that the Second Circuit applies a proximate cause test for RICO standing, *not* the indirect purchaser rule. *Id.*

The Circuit cases Defendants cite all pre-date *Bridge* and involved (or hypothetically discussed) plaintiffs with purely derivative damages where other parties were better-situated to sue. *See Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 619 (6th Cir. 2004) (*reversing* dismissal of RICO claim brought by employees, *rejecting* defendant's standing argument because no other party better-situated to sue, no apportionment issues, and measure of damages readily ascertainable); *McCarthy v. Recordex Serv., Inc.*, 80 F.3d 842, 852, 856 (3d Cir. 1996) (plaintiffs conceded that if they lacked antitrust standing, they also lacked RICO standing, and plaintiffs' attorneys were the ones directly injured, not plaintiffs); *Carter v. Berger*, 777 F.2d 1173, 1174, 1177-78 (7th Cir. 1985) (injuries too attenuated because plaintiffs alleged higher tax bills—an impossible calculation—and their injury derivative of county, which sued). Defendants lean

[21] *See Schwab*, 449 F. Supp. 2d at 1054 ("The Second Circuit… based its holding in *Sperber* on the fact that plaintiffs were not targets of the racketeering enterprise, and that defendant did not deceive plaintiffs with regard to the relevant stocks. In the case before the court, plaintiffs allege that they were the intended targets of defendants' fraud, and that the defendant manufacturers deceived them into buying 'light' cigarettes.").

heavily on *In re Zantac (Ranitidine) Prod. Liab. Litig.*, 546 F. Supp. 3d 1216 (S.D. Fla. 2021), but that court did not follow (or even cite) the *Bridge* RICO standing test, did not apply the proximate cause test the Second Circuit mandated in cases like *Horn* and *Alix*, and acknowledged cases going the other way.[22] On this point, *Zantac* is unpersuasive.[23]

B. Plaintiffs' RICO Claim Is Not Precluded By The FDCA

Defendants argue that "the FDCA and the FDA's monographs specifically cover—and permit"—their alleged false advertising of, and misrepresentations and omissions about, PE Products, and that Plaintiffs' RICO claims are therefore precluded. Br. at 24. They are wrong. Both the Supreme Court in *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014)—the case Defendants cite—and the Second Circuit in *Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, 843 F.3d at 64—the controlling case Defendants do not cite—rejected precisely this argument. Together, those cases hold that even in a context where the FDA acts "pursuant to its more proactive, extensive, and focused role in drug regulation," its "requirements are a floor, not a ceiling," and neither the FDCA nor FDA regulations preclude federal false advertising claims. 843 F.3d at 64 (citing *POM Wonderful*).

In *POM Wonderful*, a unanimous Supreme Court *reversed* the Ninth Circuit's ruling that the FDA's comprehensive regulation of juice labeling barred a federal false advertising claim challenging the label. 573 U.S. at 118-20. The Court also rejected the Government's narrower position that the suit was precluded "to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of the label." *Id.* (cleaned up).

[22] *Id.* at 1224 (gathering cases).

[23] *Humana, Inc. v. Biogen, Inc.*, 666 F. Supp. 3d 135 (D. Mass. 2023) and *In re Insulin Pricing Litig.*, 2019 WL 643709 (D.N.J. Feb. 15, 2019) suffer the same core defect: they do not apply the correct test.

In *Church & Dwight*, the Second Circuit followed *POM Wonderful* to reach precisely the same conclusion with respect to *drug* labels. 843 F.3d at 64. There, defendant argued, like Defendants here, that plaintiff's claim was "precluded by Congress's provision for intensive regulation of Defendant's Product by the FDA" and that therefore "it cannot be held liable for its labeling and promotional materials because those materials were under FDA 'control,' having been reviewed and approved by the FDA…." *Id.* at 62. The Second Circuit found no merit in Defendant's efforts to distinguish *POM Wonderful*" just because "the FDA did not preapprove the juice labels at issue," holding that "[w]e see no reason why the subjugation of Defendant's Product labeling to FDA regulation through the [regulatory] process should categorically immunize it from [federal false advertising] claims…regarding the regulated labeling." *Id.* at 63-64. Doing so "would distort Congress's intent to allow the Lanham Act and the FDCA to exist in tandem to serve the distinct interests each statute protects." *Id*. (citation omitted). In short, the Second Circuit expressly rejected Defendants' core argument that following the monograph immunizes them from liability under other federal laws. *POM Wonderful* and *Church & Dwight* mandate the same result here: the FDCA does not preclude Plaintiffs' RICO claims.[24]

Defendants rely on *Apotex Inc. v. Acorda Therapeutics, Inc.* 823 F.3d 51 (2d Cir. 2016), but they simply ignore the Second Circuit's subsequent controlling decision in *Church & Dwight*, which explains why *Pom Wonderful* did not apply there—and why it does not here.[25] First, the court explained that *Apotex* left open RICO liability where the at-issue language is "literally or

[24] Lanham Act competitor claims, like these claims, are premised on a deceptive scheme to mislead the consumer.

[25] The cases involving statutes that provide an *exclusive* remedy are of no help to Defendants; the FDCA is *not* such a statute. *See Palmer v. Trump Model Mgmt.*, 175 F. Supp. 3d 103, 108 (S.D.N.Y. 2016) (Immigration and Nationality Act "indicates Congress's clear intent to limit enforcement of alleged violations to administrative mechanisms.") (cleaned up); *Norman v. Niagara Mohawk Power Corp.*, 873 F.2d 634, 637 (2d. Cir. 1989) (Energy Reorganization Act is "exclusive" remedy for employee protection in nuclear energy context); *Poretsky v. Hirise Eng'g, P.C.*, 2016 WL 5678880, *3 (E.D.N.Y. Sept. 30, 2016) (National Flood Insurance Act provides "the exclusive federal remedy for conduct falling within the Program's scope.") (citation omitted).

implicitly false." 843 F.3d at 73, n.13 (quoting *Apotex*, 823 F.3d at 64 n.10). That is this case, and dispositive. Second, the court noted *Apotex* did not involve a preclusion analysis at all; instead, it addressed a "different question[] of law." *Id.* This explains why *Apotex* did not cite *POM Wonderful*. Third, in *Church & Dwight* "there [was] no claim that any fact relating to the effects of a medical product found by the FDA to be true should nonetheless be found by the court to be false." *Id.* The same is true here. The NDAC has now concluded that Oral PE is ineffective, a finding not only consistent with, but a central factual basis for, Plaintiffs' RICO claim. Plaintiffs allege Defendants knew since at least 2016 that Oral PE is ineffective, and engaged in a scheme to mislead consumers, the public, and, for purposes of their RICO claim, the FDA about that fact, to maintain FDA approval of their label. Compl. ¶¶ 8-9, 14, 54-66, 85-130, 473-80, 495, 508.

Defendants also ignore the requirement to read the statutes in harmony absent "a clearly expressed congressional intention" for one to control. *Epic Sys. Corp. v. Lewis*, 584 U.S. 497, 510 (2018) (cleaned up). They do not come close to making their "stout uphill climb" to establish preclusion. *Id.* There is *no* express language in the FDCA precluding RICO claims. When Congress amended the FDCA in 1990 to address conflicting state law, it "did *not* enact a provision addressing the preclusion of other *federal* laws…." *POM Wonderful*, 573 U.S. at 114 (emphasis added).[26] Congress "*did not* intend the FDCA to preclude requirements arising from other sources." *Id.* (emphasis added). Indeed, as discussed *supra* the Supreme Court held in *Wyeth* that "Congress did not intend FDA oversight"—and by necessary implication, the FDCA—"to be the *exclusive* means of ensuring drug safety and effectiveness." 555 U.S. at 575 (emphasis added). "[T]he FDCA protects public health and safety," *POM Wonderful*, 573 U.S. at 115 (citations

[26] The two statutes have co-existed since RICO was enacted in 1970. *See* ch. 675, 52 Stat. 1040 (1938) (FDCA); 84 Stat. 922-3 (1970) (RICO).

omitted), but its "main purpose" is "not to protect consumers from deceptive advertising." *Bayer*, 701 F.Supp.2d at 371. By contrast, "[g]uarding against false or deceptive advertising in the marketplace" is "within the province of false advertising suits…." *Id.* So, too, RICO, which provides a "tool for everyday fraud cases." *Sedima*, 473 U.S. at 499. The FDCA and RICO thus regulate separate spheres of conduct and complement, rather than conflict with, one another.

Last, to support their argument that "the Second Circuit has broadly rejected the use of RICO to allege federal regulators have been defrauded," Br. at 25, Defendants cite a filed-rate doctrine case, *Wegoland Ltd. v. NYNEX Corp.*, 27 F.3d 17, 22 (2d Cir. 1994).[27] But that doctrine renders *any* rate set by a utility "per se reasonable and unassailable in judicial proceedings," *id.* at 18, and has no application here. The law is clear that fraud against the FDA *can* be a basis for a RICO claim. *See, e.g., Meijer, Inc. v. Ranbaxy Inc.*, 2016 WL 4697331, at *11 (D. Mass. June 16, 2016), *report and recommendation adopted* (Sept. 7, 2016) (holding the FDA does not police antitrust or RICO, including claims of fraud committed against it.); *see also In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694 (2d Cir. 2009) (reversing dismissal of fraud-based antitrust claims related to fraudulent FDA submissions). Thus, while the RICO claim does not rest entirely on Defendants' fraudulent FDA submissions, they are one aspect of the larger scheme to defraud consumers and the public, and to maintain FDA approval of Oral PE.

CONCLUSION

For all of these reasons, Plaintiffs respectfully request that the Court deny Defendants' motion in its entirety, and grant such other and further relief as the Court may deem just and proper. In the alternative, Plaintiffs request leave to amend to cure any deficiencies.

[27] *Se. Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 410 (11th Cir. 2011) is an unpublished Eleventh Circuit case dismissing a RICO claim for failure to adequately allege proximate cause.

Dated: July 15, 2024

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